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| APPLICATION NO.                           | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------|------------------|
| 10/595,911                                | 05/19/2006  | Yoshiaki Washio      | PB60581USW               | 8939             |
| 23347                                     | 7590        | 12/17/2008           | EXAMINER                 |                  |
| GLAXOSMITHKLINE                           |             |                      | DAVIS, ZINNA NORTHINGTON |                  |
| CORPORATE INTELLECTUAL PROPERTY, MAI B482 |             |                      |                          |                  |
| FIVE MOORE DR., PO BOX 13398              |             |                      | ART UNIT                 | PAPER NUMBER     |
| RESEARCH TRIANGLE PARK, NC 27709-3398     |             |                      | 1625                     |                  |
|   |             |                      |                          |                  |
|   |             |                      | NOTIFICATION DATE        | DELIVERY MODE    |
|   |             |                      | 12/17/2008               | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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JULIE.D.MCFALLS@GSK.COM

|                              |                         |                     |
|------------------------------|-------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>  | <b>Applicant(s)</b> |
|                              | 10/595,911              | WASHIO, YOSHIAKI    |
|                              | <b>Examiner</b>         | <b>Art Unit</b>     |
|                              | Zinna Northington Davis | 1625                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 October 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-9, 13 and 14 is/are pending in the application.

4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,2,5,6,8 and 9 is/are rejected.

7) Claim(s) 3,4 and 7 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date 05/19/06.

4) Interview Summary (PTO-413)

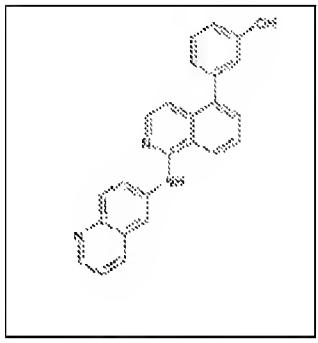
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Claims 1-9, 13, and 14 are pending.
2. Claims 10-12, 15, and 16 have been cancelled.
3. In the response filed October 13, 2008, Applicants have elected Group I, claims 1-9, without traverse. Applicants also identify the compound of Example 15 as the preferred species. The compound is depicted below:



4. Based upon the response filed October 13, 2008, the election of species requirement is withdrawn. However, the restriction requirement is maintained.
5. Claims 13 and 14 are withdrawn from consideration. These claims have not been canceled.
6. Rejoinder of the method claims will be addressed upon allowance of claimed subject matter.
7. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 8, and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making a solvate of the claimed compounds.

The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. "The factors to be considered in making an enablement rejection have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546.

- a) Determining if any particular substrate would form a solvate would require synthesis of the substrate and subjecting it to recrystallization with a variety of solvents, temperatures, pressures, and humidity. The experimentation is potentially open-ended.
- b) The direction concerning the solvate is found on page 9, which simply states solvate is formed a solute.

c) There is no working example of any solvate formed. The claims are drawn to solvates, yet the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here. There is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

d) The nature of the invention is chemical synthesis, which involves chemical reactions.

e) The state of the art is that is not predictable whether solvates will form or what their composition will be. In the language of the physical chemist, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Reference U). The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, of Reference U, West says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometry of the formed solvate, i.e. if one, two, or a half a molecule of solvent added per molecule of host. In

the same paragraph on page 365 West (Solid State Chemistry) explains that it is possible to make meta-stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent or even the moisture of the air that might change the stable region of the solvate.

f) The artisan using Applicants invention to prepare the claimed compounds would be a process chemist or pilot plant operator with a BS degree in chemistry and several years of experience.

g) Chemical reactions are well-known to be unpredictable, *In re Marzocchi*, 169 USPQ 367, *In re Fisher*, 166 USPQ 18.

h) The breadth of the claims includes all of the thousands of compounds of formula I as well as the presently unknown list of solvents embraced by the term "solvate".

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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11. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 6, 1<sup>st</sup> line, it is suggested the phrase "where in" should be amended to read as --wherein--.

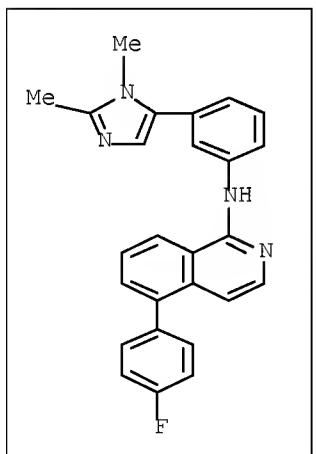
12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

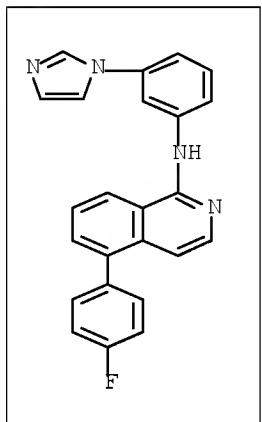
13. Claims 1, 2, 5, and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fujisawa Pharmaceutical Co., LTD (Reference B1, cited by Applicants).

The instantly claimed compounds are disclosed. At page 91, lines 15-16, Example 15, see the named compound. The compound is depicted below:



The claims are fully met when R<sup>1</sup> is phenyl substituted by halogen and R<sup>2</sup> is phenyl substituted by a 5-membered heteroaryl ring.

At page 94, lines 25-26, Example 22, see the named compound. The compound is depicted below:



The claims are fully met when R<sup>1</sup> is phenyl substituted by halogen and R<sup>2</sup> is phenyl substituted by a 5-membered heteroaryl ring.

14. The Information Disclosure Statement filed May 19, 2006 has been considered.
15. Claims 3, 4, and 7 are objected to.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.
17. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications.
18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zinna Northington Davis/  
**Zinna Northington Davis**  
**Primary Examiner**  
**Art Unit 1625**

Znd  
12.11.2008